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UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

FEDERAL TRADE COMMISSION, Plaintiff, v. APPLIED FOOD SCIENCES, INC., a corporation, Defendant.	Civ. No. 1-14-cv-00851 COMPLAINT FOR PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF

Plaintiff, the Federal Trade Commission ("FTC"), for its Complaint alleges:

1. The FTC brings this action under Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b), to obtain permanent injunctive relief, rescission or reformation of contracts, restitution, the refund of monies paid, disgorgement of ill-gotten monies, and other equitable relief for Defendants' acts or practices in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, in connection with the sale and

marketing of GCA®, also known as Green Coffee Antioxidant, a green coffee bean extract used in dietary supplements and foods.

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337(a), and 1345, and 15 U.S.C. §§ 45(a) and 53(b).

3. Venue is proper in this district under 28 U.S.C. § 1391(b) and (c), and 15 U.S.C. § 53(b).

PLAINTIFF

4. The FTC is an independent agency of the United States Government created by statute. 15 U.S.C. §§ 41-58. The FTC enforces Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), which prohibits unfair or deceptive acts or practices in or affecting commerce. The FTC also enforces Section 12 of the FTC Act, 15 U.S.C. § 52, which prohibits false advertisements for food, drugs, devices, services, or cosmetics in or affecting commerce.

5. The FTC is authorized to initiate federal district court proceedings, by its own attorneys, to enjoin violations of the FTC Act and to secure such equitable relief as may be appropriate in each case, including rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies. 15 U.S.C. § 53(b).

DEFENDANT

6. Defendant Applied Food Sciences, Inc., ("Defendant" or "AFS") is a Delaware corporation that has its principal place of business in this District and transacts, or has transacted, business in this District and throughout the United States. At all times material to this Complaint, acting alone or in concert with others, AFS has manufactured, advertised,

marketed, distributed, or sold products containing GCA to producers of finished dietary supplements and foods throughout the United States.

COMMERCE

7. At all times material to this Complaint, Defendant has maintained a substantial course of trade in or affecting commerce, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

DEFENDANT'S BUSINESS ACTIVITIES

8. This case arises from AFS's sponsorship of a seriously flawed human clinical trial and AFS's susbsequent dissemination to trade customers of false and unsubstantiated weight-loss claims based on that trial. This dissemination provided trade customers with the means and instrumentalities to deceive consumers by repeating those same false and unsubstantiated weight-loss claims in marketing dietary supplements or foods containing GCA.

Dissemination of Ads

9. In 2010, AFS paid researchers in Bangalore, India, to conduct a human clinical trial that purported to assess the efficacy of a dietary supplement containing GCA in reducing weight and body fat.

10. Starting in 2011 and continuing thereafter, to induce trade customers to purchase GCA, AFS disseminated or caused to be disseminated advertising, marketing, and purported substantiation materials, including press releases, that represented the Bangalore trial as demonstrating the efficacy of GCA for weight loss and fat loss. These documents include an article purporting to describe the trial, Joe A. Vinson *et al.*, *Randomized, Double-Blind, Placebo-Controlled, Linear Dose, Crossover Study to Evaluate the Efficacy and Safety of a*

Green Coffee Bean Extract in Overweight Subjects, 2012 Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy 5, 21-27, ("published study") (Ex. A); a poster presentation (Ex. B); other summaries, including a white paper; and press releases. These press releases, attached as Exhibits C through E, included the following statements:

A. **Green Coffee Bean Extract GCA® from Applied Food Sciences Inc. Proven in Randomized, Double Blind, Placebo-controlled Study to Efficiently Aid Weight Loss Lower Body Mass**

* * *

. . . A 22-week crossover study was conducted to examine the efficacy and safety of a commercial green coffee bean GCA® at aiding weight loss and lowering body mass in 16 overweight adults.

* * *

Significant reductions were observed in body weight (-8.04 ± 2.31 kg), body mass index (-2.92 ± 0.85 kg/m2), and percent body fat (-4.44% ± 2.00%), as well as a small decrease in heart rate (-2.56 ± 2.85 beats per minute)[.]

* * *

A 22-week crossover study was conducted to examine the efficacy and safety of a commercial green coffee extract product GCA® at reducing weight and body mass in 16 overweight adults. The green coffee extract utilized for this study was provided by Applied Food Sciences Inc [sic] (Austin, TX) under the trade name GCA®.

* * *

In looking at the individual effects of the GCA; 16 of 16 lost weight, 16/16 had decreased percent body fat[,] 16/16 had a reduction in BMI . . . .The results of the study are much more dramatic for weight loss and BMI than previous green coffee extract investigations.

(Ex. C, February 2, 2012, press release.)

Dr. Joe Vinson to Speak at ACS National Meeting & Expo on Applied Food Sciences' Green Coffee Extract GCA™ as a Weight Management Tool in the Reduction of Body Mass

* * *

Most recently in a randomized double blind placebo-controlled crossover study GCA was proven to aid in weight loss when combined with controlling diet and exercise.

(Ex. D, March 7, 2012, press release.)

B. **Dr. Oz Show Highlights GCA® Green Coffee Bean Extract from Applied Food Sciences Inc., Proven in Recent Human Study to Lower Body Mass Index and Aid in Weight Management**

After a ground breaking study was presented at the American Chemical Society Meeting in San Diego (March 2012) green coffee bean extract is becoming all the buzz in weight management products. With staggering results participants in the study lost an average of 10% of their body weight without changing diet or exercise. This phenomenal green coffee extract GCA® from Applied Food Sciences was highlighted on the Dr. Oz show.

(Ex. E, May 9, 2012, press release.)

11. Starting in 2011 and continuing thereafter, AFS furnished copies of its advertising, marketing, and purported substantiation materials, including Exhibits A through E, to its trade customers. In communications with dozens of potential trade customers, AFS used these substantiation materials to promote the sale of GCA for weight loss and fat loss, leading to a substantial increase in GCA sales. One or more trade customers have used these materials to market products containing GCA to consumers nationwide. In addition, one or more trade

customers have used these same substantiation materials to market products that contain other green coffee extract to consumers nationwide.

Origin of the Published Study: A Flawed Trial

12. AFS based its claims on a 2010 clinical trial it sponsored in Bangalore, India. As detailed below, during and after the trial, the principal investigator repeatedly: (1) altered the weights and other key measurements of the subjects; (2) changed the length of the trial; and (3) confused which subjects took either the placebo or GCA at various points during the trial. When the principal investigator failed to find a publisher for his summary of the purported trial, AFS hired ghost-writers, who – like AFS – themselves received numerous, conflicting data sets from the principal investigator, but accepted the final version as correct. The published study does not refer to these inconsistencies. Moreover, the published study fails to explain why most of the reported weight loss occurred when subjects were taking neither GCA nor a placebo; and fails to disclose that subjects were exercising and/or dieting during portions of the trial.

13. Specifically, in 2010, AFS hired Mysore Nagendran, M.D., then of the Trinity Hospital and Heart Foundation in Bangalore, India, to conduct the above-referenced crossover clinical trial to study "the efficacy and safety" of GCA in overweight but non-obese subjects, *i.e.*, subjects with a Body Mass Index (BMI) ranging from 25 to 30. AFS, as the study sponsor, and Nagendran, as the study monitor, approved the protocol for the "double-blinded, placebo controlled" trial. The AFS protocol specifies that after ineligible recruits were screened out, sixteen test subjects selected for participation would be randomly assigned to three groups, each of which would take either a high-dose GCA (350 mg. capsules three times

a day), a low-dose GCA (350 mg. capsules two times a day), or a placebo (inert capsules three times a day), for six weeks; take nothing for a two-week "washout" period; rotate to a second six-week treatment arm, followed by a second washout period; and end with a third six-week treatment arm, such that all subjects were exposed to the high dose, low dose, and placebo over twenty-two weeks.

14. In reporting the results of the purported trial to AFS, Nagendran, the study monitor in Bangalore, repeatedly altered the subjects' weights and other data.

15. In February of 2011, AFS summarized Nagendran's initial data in an internal report that described a 20-week study in which subjects lost, on average, 14.6 pounds during the two GCA arms of the study (high dose and low dose). This contrasts with the published study, which describes a 22-week study in which subjects lost, on average, only 7.9 pounds during the two GCA arms. (Ex. A.)

16. On March 25, 2011, Nagendran submitted new data regarding the Bangalore trial to AFS in the form of a draft manuscript entitled, "An Open labeled Prospective linear crossover study to evaluate the efficacy and safety of CGA[sic]." This draft described a 24-week trial and listed (among other discrepancies) different final weights for eleven of the sixteen subjects compared to the data set used for the published study. Moreover, the description of the trial as "open label" in the title suggests that both the administrators and the subjects may have known what subjects were taking during the trial. Nagendran failed to find a publisher for the manuscript.

17. AFS then sent the manuscript to Joe A. Vinson and Bryan Burnham, both professors at the University of Scranton, to revise the draft and submit it for publication. Neither Vinson nor Burnham played any role in designing or executing the trial.

18. In preparing the study for publication, Vinson and Burnham found numerous data discrepancies. Twice, in response to questions from Vinson about these discrepancies, Nagendran provided new data sets to Vinson and AFS, each time explaining that the new version corrected previous errors. First, on or about July 29, 2011, Nagendran sent Vinson and AFS a revised data set that indicates a 28-week study and contains different dates and measurements than the manuscript. Second, on or about August 5, 2011, Nagendran sent Vinson and AFS another data set − the set ultimately used for the published study. The August 5, 2011, data set again altered various measurements and provided new final weights for six of the sixteen subjects. Despite these discrepancies, Vinson, Burnham, and AFS did not check the revised data sets against the raw data, which they never reviewed. Rather, Vinson, Burnham, and AFS relied solely on Nagendran's assurance that the data set provided on August 5, 2011, was accurate.

19. In October of 2011, AFS paid Nagendran to present a poster at a Cleveland Clinic event. This poster (Ex. B), which AFS subsequently disseminated to numerous trade customers, indicates different total weight losses for eleven of the sixteen subjects compared to the data set used for the published study.

20. Yet another data set emerged on September 12, 2013, when AFS produced handwritten "summary sheets" for each of the sixteen subjects. Nagendran and his assistant initialed each of the sixteen summary sheets. These summary sheets, which contain numerous

crossed-out figures, indicate different final weights for twelve of the sixteen subjects compared to the data set used for the published study.

21. The numerous data sets also vary as to the crossover sequence – who took the high dose, low dose, or placebo at any point during the trial. When combined with the other anomalies described above, these discrepancies preclude a reliable determination of the length of the trial; the weights of subjects at various points during the trial and at the trial's conclusion; and when subjects took the high dose, low dose, or placebo.

22. The study's findings regarding weight loss suffer from two additional flaws, both of which concern the washout periods between treatment arms. First, the study indicates that the sixteen subjects, on average, lost 17.7 pounds total, but lost the majority of that weight – 10.5 pounds – during the two, two-week washout periods when the subjects were taking nothing. *Compare* Ex. A at Table 1 (indicating weight at start and end of twenty-two weeks) *with* Table 2 (indicating that, on average, subjects lost 4.5 pounds and 3.4 pounds during the two treatment arms, respectively, and gained 0.7 pounds during the placebo arm). Based on these data, subjects lost more weight, and at a faster rate, during the two washout periods in which subjects were not taking anything than when they were taking GCA or a placebo.

23. Second, as indicated on Figure 1 of the published study (Ex. A), the six subjects who purportedly began the trial on the placebo experienced a precipitous weight loss during the two-week washout period after they stopped taking the placebo and before they began their first GCA arm. The study's supporting data indicates that these persons, who at that point had never taken GCA, lost, on average, 11.9 pounds during these two weeks. Weight loss of that

magnitude over that time period without changing diet is extremely unusual, if not impossible, and undermines the reliability of all of the study data.

24. Separate from these anomalies, the published study fails to disclose that the protocol provided for subjects to undergo daily, 400-calorie workouts during the first two arms of the trial, when most of the reported weight loss occurred, and to restrict their caloric intake during the second arm.

25. In addition, the study suffers from other design and methodological flaws, including its failure to document how the subjects and administrators were blinded, if at all, particularly where subjects were instructed to take a different number of capsules (two a day) for the low-dose GCA, compared to the high-dose GCA and placebo (three a day); its failure to report how randomization occurred; and its failure to disclose whether the subjects exercised during the study.

26. As detailed above, the study either was never conducted or suffers from flaws so severe that no competent and reliable conclusions can be drawn from it.

VIOLATIONS OF THE FTC ACT

27. Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), prohibits "unfair or deceptive acts or practices in or affecting commerce."

28. Misrepresentations or deceptive omissions of material fact constitute deceptive acts or practices prohibited by Section 5(a) of the FTC Act.

29. Section 12 of the FTC Act, 15 U.S.C. § 52, prohibits the dissemination of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics. For the purposes of

Section 12 of the FTC Act, 15 U.S.C. § 52, GCA is either a "food" or "drug" as defined in Section 15(b) and (c) of the FTC Act, 15 U.S.C. § 55(b) and (c).

Count I

False or Unsubstantiated Efficacy Claims

30. Through the means described in Paragraphs 8 through 26, Defendant has represented, directly or indirectly, expressly or by implication, that GCA causes substantial weight loss and fat loss, including:

A. 17.7 pounds (8.04 kilograms), 10.5% of body weight, and 16% of body fat, without diet or exercise, in twenty-two weeks; and

B. 17.7 pounds (8.04 kilograms), 10.5% of body weight, and 16% of body fat, when combined with diet and/or exercise, in twenty-two weeks;

31. The representations set forth in Paragraph 30 above are false or were not substantiated at the time the representations were made.

32. Therefore, the making of the representations as set forth in Paragraph 30 above constitutes a deceptive act or practice and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

Count II

False Proof Claims

33. Through the means described in Paragraphs 8 through 26, AFS has represented, directly or indirectly, expressly or by implication, that a clinical study proves that GCA, when taken as a dietary supplement or other formulation, causes substantial weight loss, including

an average weight loss of 17.7 pounds, and reduces overall body weight by 10.5% and overall body fat by 16%, with or without diet or exercise, in twenty-two weeks.

34. In truth and in fact, a clinical study does not prove that GCA, when taken as a dietary supplement or other formulation, causes substantial weight loss, including an average weight loss of 17.7 pounds, and reduces overall body weight by 10.5% and overall body fat by 16%, with or without diet or exercise, in twenty-two weeks.

35. Therefore, the making of the representation as set forth in Paragraph 33 above constitutes a deceptive act or practice and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

Count III

Means and Instrumentalities

36. AFS has provided to its trade customers advertising, marketing, and purported substantiation materials referred to in Paragraphs 10-11, containing, among other things, false and unsubstantiated representations, as described in Paragraphs 8 through 26 above.

37. By providing its trade customers with these advertising, marketing, and purported substantiation materials, AFS has provided its trade customers the means and instrumentalities for the commission of deceptive acts and practices. Therefore, AFS's practice described in Paragraph 36 above constitutes a deceptive act or practice, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

CONSUMER INJURY

38. Consumers have suffered and will continue to suffer substantial injury as a result of AFS's violations of the FTC Act. In addition, AFS has been unjustly enriched as a result of

its unlawful acts or practices. Absent injunctive relief by this Court, AFS is likely to continue to injure consumers, reap unjust enrichment, and harm the public interest.

THIS COURT'S POWER TO GRANT RELIEF

39. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to grant injunctive and such other relief as the Court may deem appropriate to halt and redress violations of any provision of law enforced by the FTC. The Court, in the exercise of its equitable jurisdiction, may award ancillary relief, including rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies, to prevent and remedy any violation of any provision of law enforced by the FTC.

PRAYER FOR RELIEF

Wherefore, Plaintiff FTC, pursuant to Section13(b) of the FTC Act, 15 U.S.C. § 53(b), and the Court's own equitable powers, requests that the Court:

A. Enter a permanent injunction to prevent future violations of the FTC Act by Defendant;

B. Award such relief as the Court finds necessary to redress injury to consumers resulting from Defendant's violations of the FTC Act, including, but not limited to, rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies; and

C. Award Plaintiff the costs of bringing this action, as well as such other and additional relief as the Court may determine to be just and proper.

Respectfully submitted,

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General Counsel

Dated: September 8, 2014

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